

MEMORANDUM

TO: All Pharmacy Licensees

FROM: Massachusetts Board of Pharmacy

DATE: August 2, 2016

SUBJECT: Compounding of Commercially Available Drug Products

Based on various pharmacy investigations, the Board wishes to remind all licensees of federal laws regarding the compounding of commercially available products.

In accordance with the federal Food, Drug, and Cosmetic Act, a pharmacy may not compound, regularly or in inordinate amounts, any drug that is essentially a copy of a commercially available drug product. 21 U.S.C. § 353a(b)(1)(D).

Please note the FDA recently released draft guidance titled *Compounded Drugs that are Essentially Copies of Commercially Available Drugs*. The Board strongly recommends all licensees review the following draft guidance:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf>

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510153.pdf>